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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,624	07/25/2003	Takayuki Kohchi	026350-087	9637
21839	7590	01/17/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			YU, GINA C	
		ART UNIT	PAPER NUMBER	
		1617		

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/626,624	KOHCHI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 19-21 and 25-27 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. <u>200601</u> .                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

The present Office action replaces the previously issued Office action dated October 7, 2005, as the preliminary amendment dated July 25, 2003 had been not been considered. Claims 19-27 are pending.

This application appears to be a division of Application No. 09/931,075, filed on August 17, 2001. A divisional application is a later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application. See MPEP § 201.06. As the result of the restriction requirement made by the examiner on September 10, 2002 during the prosecution of the parent application, composition claims were elected. In the present case, claims 22-24 are composition claims, which are directed to the invention that applicants have already elected in the parent application. Thus, claims 22-24 are withdrawn from consideration in this divisional application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 19, 20, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Okubo et al. (JP 9-241637-A, English Translation) (“Okubo”).**

Okubo discloses in Table 1 that 0.01-20 mM of citrulline provides antioxidant effect. See Translation, [0086]-[0097]. The reference also discloses in paragraphs

[0080]-[0084] that citrullin, along with epigallocatechin, is mixed and incorporated into pharmaceutical agents, food, and in cosmetics to improve the shelf-life of the products.

While Okubo does not expressly mention a method of treating skin by applying the citrulline-containing composition as recited in claim 19, the claimed method is anticipated since the topical application of the prior art pharmaceutical or cosmetic composition is the inherent use of the product. Since the prior art teaches citrulline-containing cosmetic compositions, it is viewed that "active oxygen in the skin is scavenged by the citrulline" when the user applies the composition to the skin according to the intended use of the product.

**Claims 19-21 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ennen et al. (WO 95/15147) ("Ennen").**

Ennen discloses cosmetic composition comprising L-citrulline. See abstract. The reference teaches in p. 16, formulation 6 of the original document that 2.5 % of citrulline (MW 175.2) is used in a composition. Thus about 0.143 M, or 143 mM concentration of citrulline is present in the composition, meeting the present claim 21.

While Ennen does not expressly mention a method of treating skin by applying the citrulline-containing composition as recited in claim 19, the claimed method is anticipated since the topical application of the prior art topical composition is the inherent use of the product. Since the prior art teaches citrulline-containing topical compositions, it is viewed that "active oxygen in the skin is scavenged by the citrulline" when the user applies the composition to the skin according to the intended use of the product.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okubu in view of Ennen et al. (WO 95/15147).**

While Okubu et al. teach that citrulline effectively provides antioxidant effect the reference does not mention the specific amount as required by the present claim. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955).

Given the teaching of the antioxidant efficacy of citrulline in cosmetics in Okubu, a skilled artisan would have obviously discovered a workable weight range of citrulline by routine experimentation. A skilled artisan would have been motivated to increase the amount of citrulline in expectation of obtaining increased antioxidant effect.

**Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh (US 5874471).**

Waugh discloses a method of using citrulline as an oral supplement. See Examples and Dietary Formulations in col. 10, line 40 – col. 17, line 53. See instant claims 1, 2, 7. The reference teaches that administration of citrulline, a precursor of L-arginine, is effective in increasing endogenous production for nitric oxide and managing atherosclerosis, which is "considered to be a free radical disease". See col. 5, line 23 – col. 7, line 11. See also col. 7, lines 40 – 53 for the teaching that increasing L-arginine level in cell alleviates oxidative stress.

### ***Conclusion***

No claims are allowed.

Claims 19-21 and 25-27 are rejected.

Claims 22-24 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

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The examiner can normally be reached on Monday through Friday, from 9:00 AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



GREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER